REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein.

Claims 24 and 28 have been amended to clarify their meaning, but no new matter not already present in the claims or specification has been added.

In the Office Action of July 13, 2007, the Examiner took the following actions to which Applicant herein makes response: (1) again noted use of a trademark and indicated that it should be capitalized and that other instances should be corrected as well and stated that generic terminology on TWEEN and EXTRAVIDIN should accompany trademarks; (2) withdrew the objection to claims 24-26, 28, 30-33 and 37-39, stating that these claims are dependent on non-elected claims; that claims 31 and 32 are substantially duplications and the claims 38 and 39 are substantially duplicates; (3) withdrew various rejections of the claims under Section 112 and 102(b); (4) maintained the rejection of claims 24-25 and 28 under 35 USC 112, first paragraph with respect to the written description requirement, stating that Applicant had not fully characterized the antigen nor stated what epitopes would allow differentiation between species nor described the antibodies specifically enough; (5) maintained the rejection of claims 24-25 and 28 under 35 USC 112, first paragraph with respect to the enablement requirement, stating that the laboratory designations are not sufficient to provide enablement, that the specification is silent with respect to what "immunoepitope" meets the limitations of the claims; (6) maintained the rejection under 35 USC 112, second paragraph stating that "mucocutane candidiasis is a disease caused by a fungal infection and is not the disease itself; (7) maintained the rejection of claims 24 and 28 under 35 USC 102(b) as being anticipated by Wakshull; (8) newly rejected clams 24-25 and 28 under 35 USC 112, second paragraph stating that based on the sentence structure and use of commas it is not clear which epitopes are in;.These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 24-25 and 28 now pending in the application.

Use of trademark

Applicant has amended page 8 of the specification to capitalize the two cited trademarks and to indicate that they are trademarks, and to provide descriptive information obtain from the product literature for these products. Copies of the product literature are attached hereto. The undersigned attorney has reviewed the specification again and has not located any other trademarks. Applicant therefore submits that this objection has been overcome.

Rejection of claims 24-25 and 28 under 35 USC 112, first paragraph with respect to the written description requirement

The Examiner states that Applicant has not fully characterized the antigen or antibodies and that "one would be unable to differentiate between plant species and particular fungal species" and that the specification is "silent regarding what epitopes would allow one to differentiate between species". Applicant respectfully submits that Applicant's claimed invention for "diagnosis of a Candida fungal infection in a human patient" in which a mucosal or urine sample is analyzed allows determination that there is a fungal infection, and that it is well-known that if there is a fungal infection of a human this infection is likely to be Candida. A positive result of the invention herein, when a mucosal or urine sample is analyzed allows the person doing the analysis to know that there is a fungal infection, and that such an infection in which there antigens found in such samples would likely be a Candida infection. It is further known that plant infections are not a typical human problem, so one of ordinary skill in the art would not normally be worried about plant infections, nor find such infections upon such analysis.

It is clear from Applicant's disclosure that use of a monoclonal antibody reactive with a β(1-3) glucan – and/or a β(1-3)(1-6) – glucan epitope in free form, in cell wall fragments or on an intact cell surface and available in cell wall fragments would be useful in detecting fungal infections, in particular, the Candida infections discussed. It is well known in the art how to prepare antibodies for such antigens and such methodology would clearly allow one of ordinary skill in the art to do so. What is unique and claimed herein is the diagnosis of a fungal infection in a human patient comprising assaying mucosal secretions or urine of the patient as claimed. One does not need to know which

epitope is allowing the diagnosis, but rather just how to carry out methods known in the art to accomplish the results of Applicant's unique invention.

The Examiner cited the Noelle case stating that Noelle did not provide sufficient support for claims to a particular antibody. Applicant respectfully submits that the claims pending herein are not claims to antibodies or to any other substance, but rather are method claims for diagnosis. The Examiner's statement that "applicant has failed to 'fully characterize' the antigen ... to which the claimed antibody binds" is therefore not relevant, as the claims are not to an antibody, but rather to a method of using antibodies.

The Examiner also states that the specification does not describe the antibodies specifically enough. Applicant respectfully submits that it is the activity of the antibody which is of use herein, and that it is well known in the art how to obtain antibodies to antigens as discussed in the specification, and that one does not need to know the specifics about an antibody if one has an antibody with certain characteristics and uses it according the claimed, and well-characterized invention herein.

Applicant therefore submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, first paragraph with respect to the written description requirement.

Rejection of claims 24-25 and 28 under 35 USC 112, first paragraph with respect to the enablement requirement

The Examiner states that the specification fails to describe the immunoepitopes against which the "claimed antibodies" are raised and must subsequently bind. Applicant respectfully incorporates herein the remarks made above, and in particular the fact that there are no "claimed antibodies" herein. Rather the pending claims herein are for methods of using antibodies that have been prepared against particular antigens. One of ordinary skill in the art can prepare and use such antibodies according to the claimed invention without further information or experimentation, and thus the claimed invention is fully enabled.

The Examiner states that applicants have not shown the method to be effective, yet Applicant has provided examples showing reaction of the antibodies against the antigens in serum. The Examiner states that the "skilled artisan" would expect that urine

samples would not be predictive of dermatophytic infections, and that oral samples would not be predictive of vaginal infections. Applicant submits that if this is true, it is further evidence that the skilled artisan **would** know which type of sample to test with Applicant's method for which type of infection, and thus this further evidence of the enablement of Applicant's invention to one of ordinary skill in the art.

Applicant therefore submits that claims 24, 25 and 28 pending herein are patentable under 35 USC 112, first paragraph with respect to the enablement requirement.

Rejection under 35 USC 112, second paragraph stating that "mucocutane candidiasis is a disease caused by a fungal infection and is not the disease itself

Applicant respectfully submits that the pending claims (24 and 28) have been amended to recite: wherein the fungal infection is Candida vaginitis or mucocutane candidiasis. If the Examiner finds this language to still be unclear, Applicant respectfully requests that the Examiner suggests language that would overcome this rejection.

Rejection of claims 24 and 28 under 35 USC 102(b) as being anticipated by Wakshull

Applicant respectfully submits that the language of claim 25 with respect to "Candida vaginitis or mucocutane candidiasis" has been added to pending claims 24 and 28, which were not rejected on the basis of Wakshull. It is therefore submitted that claims 24 and 28 as amended herein are similarly patentable over Wakshull.

New rejection of claims 24-25 and 28 under 35 USC 112, second paragraph stating that based on the sentence structure and use of commas it is not clear which epitopes are in

Applicant respectfully submits that claims 24 and 28 recite in part: A method for the diagnosis of a fungal infection in a human patient comprising assaying mucosal secretions or urine of the patient with at least one antibody reactive with a Candida β(1-3) glucan – and/or a β(1-3)(1-6) – glucan epitope in free form~~, in cell wall fragments or on an intact cell surface and~~ or available in cell wall fragments of *C. albicans* ~~and/~~or *C. neoformans*, or on the cell surface of *C. albicans*, *C. parapsilosis*, *C. krusei*, *C. glabrata*

and/or *C. neoformans*... It is clear from Applicant's disclosure that both epitopes can be in free form, in cell wall fragments, or on the cell surface (see for example, page 2, lines 30-35). If the Examiner feels that a different way of wording the claims would more clearly state that fact, Applicant would welcome a suggested change in wording, but Applicant respectfully submits that this is the clear meaning of the claims as amended herein.

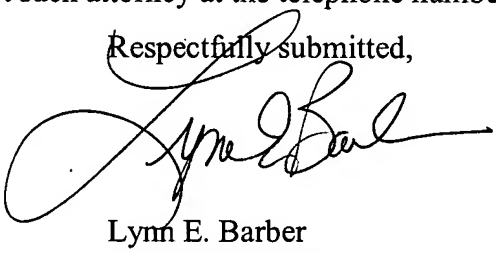
Conclusion

For all the foregoing reasons, claims 24 and 28 are submitted to be fully patentably distinguished over the cited reference and in allowable condition. Favorable consideration is therefore requested.

No new claims have been added to the previously pending claims. It is therefore believed that no fee is required for the presentation of this amendment except for the separately submitted Petition for Extension of Time. Any additional amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



Lynn E. Barber
Attorney for Applicants
Registration No. 31,734
P.O. Box 16528
Fort Worth, TX 76162
(817) 361-7131

Enclosures:
Petition for Extension of Time and fee
Copies of product literature for TWEEN™ and EXTRAVIDIN™

EXTRA3 Rabbit ExtrAvidin® Peroxidase Staining Kit antibody produced in goat

Sigma

Synonym ExtrAvidin® Peroxidase Staining Kits

Expand/Collapse All

Price and Availability

Click For Pricing and Availability

Descriptions

Components
3 mL ExtrAvidin®-Peroxidase
3 mL Biotinylated Secondary Antibodies
Complete Instructions and Assay Protocols

Features and Benefits
- Use in immunohistology, ELISA, and immunoblotting assays.
- Monoclonal Anti-Goat IgG antibodies in EXTRA-1 show no cross-reactivity with human IgG. These antibodies also recognize sheep IgG.
- Affinity Isolated Antibodies in EXTRA-2, EXTRA-3 and EXTRA-6 have been adsorbed with human IgG and IgM to minimize cross-reactivity.
- Biotinylated antibodies contain a spacer which improves accessibility for the ExtrAvidin® conjugates.

General description
These kits comprise universal reagents for use with primary antibodies in immunohistology, ELISA, and immunoblotting.
ExtrAvidin® is a unique form of avidin, available only from Sigma, that combines the high specificity and affinity of avidin for biotin with low non-specific binding at physiological pH. ExtrAvidin® peroxidase exhibits high sensitivity with low background.

Legal Information
ExtrAvidin is a registered trademark of Sigma-Aldrich Biotechnology LP and Sigma-Aldrich Co.

Properties

usage
sufficient for 2,000 tests ELISA, Dot blot
sufficient for 200 tests Immunohistology

shipped in wet ice

storage temp. 2-8°C

Safety

WGK Germany 3

Related Categories

... Kits > **ExtrAvidin® Staining Kits**
... Kits > **Immunohistology Kits**
... Alphabetical Index > **R**
... by Animal > **Rabbit Secondary Antibodies and Conjugates**

Related Information
Celltransmissions 19(1) (180kb)
EXTRA3 - Bulletin (95kb)
MSDS
Certificate of Analysis
Enter Lot No. GO
More Information
Links
Related Categories
Page Options
Print Preview
Bulk Quote
Ask A Scientist
Email Page

Last 5 Products Viewed
EXTRA3 (Sigma)

3050 Spruce Street
Saint Louis, Missouri 63103 USA
Telephone 800-325-5832 • (314) 771-5765
Fax (314) 286-7828
email: techserv@sial.com
sigma-aldrich.com

ProductInformation

TWEEN® 20

Product Number **P 5927**
Store at Room Temperature

Product Description
CAS No: 9005-64-5
Appearance: Clear, yellow to yellow-green viscous liquid
Boiling point: >100 °C
Brookfield Viscosity: 370-430 cps (25 °C, neat)
pH of 1% aqueous solution: 5-7
Refractive index: 1.4685[1]
Specific gravity: 1.1
HLB (hydrophile-lipophile balance) value: 16.7[2]
CMC value[3]: 60 mg/l
Structure: TWEEN 20 is a polyoxyethylene sorbitol ester, with a calculated molecular weight of 1,225 daltons, assuming 20 ethylene oxide units, 1 sorbitol, and 1 lauric acid as the primary fatty acid. Fatty acid constituents of this product are determined by transesterification to yield fatty acid methyl esters, which are identified by gas chromatography.
Synonyms: Polysorbate 20; PEG(20)sorbitan-monolaurate, polyoxyethylenesorbitan monolaurate.

Product No. P5927 has been tested for suitability as a solubilizing agent of membrane proteins and as a blocking reagent in blotting applications.

TWEEN 20 is a nonionic detergent widely used in biochemical applications. Sigma offers a number of products for research, some tested for suitability in a given application. The general use reagent is Product No. P 1379. Other products are:
P 7949 is tested for trace element content.
P 9416 is tested for molecular biology use.
P 2287 is tested for cell culture use.
P 5927 is tested for electrophoresis use.
P 2690 (70% solution).

TWEEN 20 is a frequently used member of the polysorbate family. These have been used as emulsifying agents for the preparation of stable oil-in-water emulsions.[4] TWEEN 20 has been used in pre-extraction of membranes to remove peripheral proteins (used at 2% for extraction of membrane-bound proteins). Several resources may be helpful in determining usage concentrations.[5]

TWEEN 20 has been used as a blocking agent for membrane based immunoassays at a typical concentration of 0.05%. TWEEN 20 is suitable for use as a solubilizing agent of membrane proteins and as a blocking agent in Western blotting.[3] TWEEN 20 can be used for lysing mammalian cells at a concentration of 0.05 to 0.5%.

Precautions and Disclaimer
For Laboratory Use Only. Not for drug, household or other uses.

Preparation Instructions
TWEEN 20 is miscible in water (100 mg/ml), yielding a clear, yellow solution. It is also miscible with alcohol, dioxane, and ethyl acetate; and is practically insoluble in liquid paraffin and fixed oils.[4]

Storage/Stability
Aqueous solutions of polysorbates undergo autoxidation during storage, with changes being catalyzed by light, increased temperature, and copper sulfate.[6] Autoclaving is not recommended without testing for changes in properties. TWEEN 20 may not be stable to autoclaving, particularly with metal cations in buffer solutions. TWEEN 20 is heat sensitive and will darken when exposed to elevated temperatures. Polysorbates have been reported to be incompatible with alkalis, heavy metal salts, phenols, and tannic acid. Polysorbates may reduce the activity of many preservatives.[4] No plastic incompatabilities have been observed.

References
1. Sys. Analysis of Surface Active Agents, 2nd ed., p. 533.
2. Data for Biochemical Research, 3rd ed., Dawson, R. M., et al., Oxford Press (New York, NY: 1986), p. 289.
3. Helenius, A., et al., Properties of Detergents. Methods in Enzymology, **56**, 734-749 (1979).
4. Martindale The Extra Pharmacopoeia, 30th ed., Reynolds, J. E. F., ed., Pharmaceutical Press (London, England: 1993), p. 1030.

5. Neugebauer, J.M., Detergents: An Overview. Methods in Enzymology, **182**, 239-253 (1990).

6. Donbrow, M., et al., Autoxidation of polysorbates. J. Pharm. Sci., **67**, 1676-1681 (1978).

RLG/AJH 5/03